DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT - 6 2002

Mr. Dale R. Agthe
Legal Research Attorney
University of Colorado Hospital
Office of the General Counsel
P.O. Box 6508, Mailstop F-415
Aurora, CO 80045-0508

Re: Docket No. 02P-0246/CP1 & LET1

Dear Mr. Agthe:

This letter responds to your citizen petition received on May 29, 2002, and your letter dated August 13, 2002, requesting an interpretation of the phrase "pharmacies of hospitals or other health care entities" as used in section 503 of the Federal Food, Drug, and Cosmetic Act (the Act). In particular, you requested that the Food and Drug Administration (FDA) deem the pharmacy located in the University of Colorado Hospital's Anschutz Outpatient Pavilion (Anschutz Pavilion) a pharmacy of a "hospital" or "other health care entity" for the purposes of receiving and dispensing prescription drug samples. We have responded in the past to similar inquiries. For the reasons stated below, your petition is granted.

The Prescription Drug Marketing Act of 1987 (PDMA) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments of 1992 (PDA) on August 26, 1992. The PDMA, as modified by the PDA, amended various sections of the Act to, among other things, establish requirements for the distribution of human prescription drug samples. The PDMA made it unlawful, according to section 503(c)(1) of the Act, for any person to "sell, purchase, or trade or offer to sell, purchase, or trade any drug sample." In addition, section 503(d) of the Act bars any person from "distribut[ing] any drug sample." There are exceptions, however, to this prohibition. According to section 503(d)(2)-(3), a manufacturer or authorized distributor of a drug may distribute samples but only (1) to licensed practitioners or (2) upon request of a licensed practitioner, to "pharmacies of hospitals or other health care entities." Similarly, according to section 503(d)(1), the prohibition on drug sample distribution does not preclude the dispensing of prescription drug samples to patients by a (1) licensed practitioner, (2) health care professional acting at the direction and under the supervision of a licensed practitioner, or (3) "pharmacy of a hospital or of another health care entity" that is acting at the direction of a licensed practitioner. Our regulations implementing the PDMA (21 CFR part 203) codified the drug sample distribution requirements and restrictions.

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According to your petition, the Anschutz Pavilion is owned and operated by the University of Colorado Hospital, and contains a number of University of Colorado Hospital clinics providing medical treatment on an outpatient basis. The Anschutz Pavilion also houses a pharmacy (the Anschutz pharmacy) (Petition at 3).

Section 503(d) of the Act does not require a pharmacy to be a *hospital pharmacy* in order to receive and dispense prescription drug samples. The Act permits pharmacies of hospitals *or other health care entities* to receive and dispense prescription drug samples. According to § 203.3(q), a *health care entity* is "any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor." Therefore, as a provider of medical treatment on an outpatient basis, the Anschutz Pavilion is a *health care entity*, and it follows that the Anschutz pharmacy is the pharmacy of a health care entity. (For the purposes of this petition it is unnecessary to determine whether it could also be considered the pharmacy of a hospital.) The Anschutz pharmacy may receive and dispense prescription drug samples under section 503 of the Act. The Anschutz pharmacy and its employees remain subject, however, to section 503(c) of the Act, which prohibits the sale, purchase, or trade or offer to sell, purchase or trade any prescription drug sample.

For the reasons described above, your petition is granted. As the pharmacy of an entity that provides medical treatment, the Anschutz pharmacy is the pharmacy of a health care entity for the purposes of section 503 of the Act.

Sincerely yours,

John M. Taylor, III
Senior Associate Commissioner
for Regulatory Affairs

cc: Susan L. Warren, Program Administrator, Colorado State Board of Pharmacy